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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/917,236	07/30/2001	Jean Francois Michelet	P66892US0	8953

7590

06/03/2005

JACOBSON HOLMAN  
PROFESSIONAL LIMITED LIABILITY COMPANY  
400 SEVENTH STREET, N.W.  
WASHINGTON, DC 20004

EXAMINER
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YU, GINA C

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 06/03/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/917,236

Applicant(s)

MICHELET ET AL.

Examiner

Gina C. Yu

Art Unit

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 04 November 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-8 and 10-19 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-8 and 10-19 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

Receipt is acknowledged of amendment filed on November 4, 2004. Claims 1-8 and 10-19 are pending. Claim rejection made under 35 U.S.C. § 102 in view of Cameron et al. (US 6426359 B1) is withdrawn in view of applicants' claim amendment. Claim rejection made under 35 U.S.C. § 112, first paragraph, is withdrawn and a new rejection is made in view of further consideration.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-8 and 10-19 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicants claim a composition comprising non-prostanoic prostaglandin EP-2 or EP-4 receptor agonist, and a method of using there of. Also claimed is a composition further comprising prostaglandin EP-3 receptor antagonist.

Examiner views that the specification fails to convey to a skilled artisan to believe that applicants had the possession of the claimed invention because the specification fails to describe what specific compounds are actually used by applicants. The written description requirement for a claimed genus may be satisfied through

sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus. See Regents of the University of California v. Eli Lilly, 119 F.3d 1559, 1568, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997), cert. denied, 523 U.S. 1089 (1998). If a representative number of adequately described species are not disclosed for a genus, the claim to that genus must be rejected as lacking adequate written description under 35 U.S.C. 112, para. 1. See MPEP § 2163 (II)(A)(2)(a)(ii).

In this case, there is simply no disclosure of any species to represent the claimed "non-prostanoid prostaglandin EP-2 receptor agonist" "non-prostanoid prostaglandin EP-2 receptor agonist" and "prostaglandin EP-3 receptor antagonist". Applicants merely describe in the specification that by "non-prostanoid prostaglandin EP-2 or EP-4 receptor agonist" applicants mean a compound not comprising a cyclopentane ring of the type I, for attenuating, reducing or stopping the loss of head hair and other hairs". See spec. p. , lines 8 - 20. Even in examples in the specification applicants merely refer to the generic terms instead of disclosing what actual species are used. Although applicants refer to non-patent literatures to show that prostanoid prostaglandin EP-2 or EP-4 receptor agonists are known, this is not a disclosure of specifically what non-prostanoid compounds are used for their invention. Similarly, applicants does not disclose any single species of prostaglandin EP-3 receptor

antagonist that is said to be used in the invention. Aside from the fact that non-prostanoic prostaglandin EP-2 or EP-4 receptor agonists and prostaglandin EP-3 receptor antagonists are known in science community, there is no sufficient disclosure in the present application for a skilled artisan to reasonably believe that these compounds are actually used in the claimed composition and method.

***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

**Claims 1, 2, 4, 5, 10-12, and 17 are rejected under 35 U.S.C. 103 (a) as being unpatentable over Cameron et al. (US 6426359 B1) ("Cameron") in view of Flick (Cosmetic and toiletry Formulations).**

Cameron teaches pharmaceutical compositions comprising prostanoic and non-prostanoic prostaglandin EP2 receptor agonist. See col.5, lines 17- col. 9, line 62, when A in formula I is a (C3-C7) cycloalkylsulfonyl. The term "cosmetic" in the instant claim is a preamble which recites intended future use of the composition and not given any patentable weight. See MPEP § 2111.02. The reference further teaches that topical composition can be in the form of partially aqueous solutions containing 0.1 – 5 % of the active. See col. 53, lines 5 – 8; instant claim 2. The reference also discloses a suspension formulation comprising color (dyestuff in Claim 1) and benzoic acid solution (organic solvent in Claim 4). A tablet formulation is also disclosed, meeting the "solid" limitation in Claims 10 and 11. See Formulation 2. The reference also teaches using water, ethanol, propylene glycol or glycerin. See col. 52, lines 40 – 60.

The reference fails to teach the pH of the composition.

Flick teaches that a topical cream is formulated to pH 5.4. See p. 123.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the teaching of Carmeron by adjusting the pH of the topical composition to 5.4 as motivated by Flick because the latter teaches a safe pH for a topical composition.

**Claims 6-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Carmen and Flick as applied to claims 1, 2, 4, 5, 10-12, and 17 as above, and further in view of Deckers et al. (US 6372234 B1) ("Deckers").**

While Carmen teaches to employ methods of preparing pharmaceutical composition well known in the art, the reference fails to teach the limitation of the solvents and lipid phase of instant claims 6-8.

Deckers teaches that polyhydroxy alcohols are used in topical formulations generally in 0.1-99 % w/v, preferably in 1-40 % w/v; and oils are used in preferably in 2-60 % w/v. See col. 15, lines 45 – 12; col. 12, lines 25 – 34.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the invention of Carmen by formulating a topical composition by adding polyhydroxy alcohols and lipid phase as suggested by Deckers because 1) Carmen teaches that topical preparation for prostaglandin EP-2 receptor agonists can be prepared in methods well known in pharmaceutical art; and 2) because of the expectation of successfully producing a topical pharmaceutical composition.

### **Conclusion**

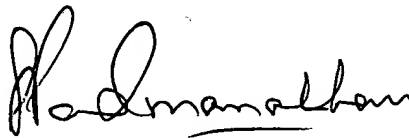
No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gina C. Yu whose telephone number is 571-272-0635.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Gina Yu  
Patent Examiner

  
**SREENI PADMANABHAN**  
**SUPERVISORY PATENT EXAMINER**